DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 11-559/S-032

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Attention: Gregory T. Brophy, Ph.D.
Director, US Regulatory Affairs

Dear Dr. Brophy:

Please refer to your supplemental new drug application dated June 1, 2001, received June 4, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Brevital sodium (methohexytal sodium for injection USP).

This "Changes Being Effected" supplemental new drug application provides for an addition to the ADVERSE REACTIONS section of the package insert.

We have completed the review of this supplemental application, and it is approved effective on the date of this letter.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Judit Milstein, Regulatory Project Manager, at (301) 827-7440.

Sincerely,

{See appended electronic signature page}

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research